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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,709

Applicant(s)

MORRIS ET AL.

Examiner

Gollamudi S Kishore, Ph.D

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The filing of RCE dated 3-29-04 is acknowledged.

Claims included in the prosecution are 18-47.

Claim Rejections - JJ USC # 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 18-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,603, 143 to Schmidt (US t 143).

US < 143 discloses vitamin active powders which are more free-flowing and stable than conventional vitamin powders.

US t 143 teaches that the composition comprises at least one fat- soluble vitamin material and a silicon containing material (c 1, 1 38 45). US \$ 143 also teaches that the vitamin be vitamin E, and further explains that vitamin E comprises a group of natural

Art Unit: 1615

substances known as tocopherols (c 2, l 55-57). It is the position of the examiner that this disclosure reads on applicant's claim to mixed tocopherols. Furthermore, 143 teaches that the silicon dioxide used in their composition has a density of around 0.2 g/cc (which is equivalent to 12.5 lbs./cu. ft.), and a particle size which passes through a 100 mesh sieve (col. 4, lines 61-62). (A 100-mesh sieve allows only particles, which are smaller than 150 microns to pass through). Thus, although 143 does not teach the specific particle size for the silica, as claimed by applicant since it teaches particles smaller than 150 microns it is the position of the examiner that the determination of a particular particle sizes from within a broad range is within the skill of the ordinary worker as part of normal optimization. Additionally, 143 does not teach the surface area of the silica. However, the burden is shifted to applicant to show that the silica disclosed by 143 does not possess the same characteristics as the silica claimed by applicant.

Lastly, 143 does not specifically use the language mixed tocopherols in describing the vitamin to be used in their composition. However as discussed before, 143 does teach that vitamin E is a group of natural substances known as tocopherol, and it further teaches that vitamin E can be used as the vitamin of the disclosed composition. Applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27). Lastly, the reference does not specifically discuss stability. However, it is the position of

Art Unit: 1615

the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. Furthermore, The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Exparte Phillips*, 28. U.S.P.Q.Zd 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Exparte Gz'tzy*, 10 USPQZd 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Therefore, it is the position of the examiner that based upon applicant's own admission, the disclosure in US & 143 teaching the use of vitamin E suggests the limitations of the instant claims. One of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E and silica. The expected result would be a free-flowing, fat- soluble vitamin powder with improved stability. Therefore, this invention as a whole would have been prima-facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the claims have been amended to indicate that the composition is a free-flowing powder. This will not overcome the rejection since Schmidt's composition is a free flowing powder (note abstract). Applicant argues that Schmidt discloses the use of three silica products to prepare their supplements, which

Art Unit: 1615

have a size distribution much greater than 150 microns and point out to table 1 of Schmidt, which according to applicant shows high retention percentages by 100 mesh sieve, which in turn indicate higher diameters. The examiner disagrees and points out to col. 4, lines 61-62 of Schmidt which show that only 9.1 percent retained on 100 mesh sieve; that means 90.9 % flows through 100 mesh which in turn indicates particles of diameter less than 150 microns. This point will also addresses applicant's argument that contrary to the examiner's assertion, there is no teaching in Schmidt that a silica product having a particle sizes less than 150 microns would be useful in preparing a free-flowing powder. Even assuming that the particle sizes are different from instant particle sizes, the examiner once again points out that the composition taught by Schmidt is 'free-flowing' and applicant has not shown any unexpected results by changing the diameter of the silica particles taught by Schmidt.

US (4,486,435) is cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK